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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,429

Applicant(s)

LEGRAIN ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-9 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-9 and newly added claims 22-24 is acknowledged.

The traversal is on the ground(s) that a search of the method of claim 1, practiced with a library prepared from a cloned viral genome that is from a virus selected from the group consisting of herpes virus, potyvirus, flavivirus and pestivirus, as in claim 3 and a search of the method of claim 1, practiced with a library prepared from HCV genome or HGV as in claim 2, does not present undue burden on the examiner. This is not found persuasive because the search would be an undue burden. The journal (literature) search is not co-extensive with US and foreign patents searches.

To examine each of the patentably distinct and independent subject matter or each groups using different databases will impose undue burden of examination.

[Applicants' arguments are moot with the cancellation of the non-elected claims.]

Status of Claims

Claims 1-4, 6-9 and 22-24 are pending and under examination in the application.

Claims 5 and 10-21 have been cancelled.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors (e.g., typographical, grammatical and/or idiomatic) of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-9 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed method recites that the library used in the method has been deposited in a depository and given an accession

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number. Since the deposited library is essential to practice the claimed invention hence, the requirement for said deposit, necessary to enable the practice of the claimed invention, has not been fulfilled. See e.g., MPEP 2408.

Claims 1, 3-4, 6-9 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the viral interaction of the specific proteins of hepatitis virus using the specifically deposited libraries, does not reasonably provide enablement for any type of viruses with any type of protein-protein interaction, peptide expressed from the library, any kind of library used in the method and the different variants of the expressed peptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure teaches a method for detecting viral protein-protein interaction specifically for the hepatitis i.e., a protein contained in said virus. However, the claims cover a wide variety of protein-protein interactions from numerous viruses and/or protein interactions from the same virus or different viruses. The generic claims to the use of viruses and cells do not appear to be within the scope of reasonable experimentation. The factors to be considered in a determination of undue experimentation are disclosed in *In re*

Wands, (U.S.P.Q. 2d 1400 (CAFC 1988)). These factors include: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the predictability of the art and the breadth of the claims.

- 1) The specification fails to give adequate direction and guidance in how to readily go about determining which are the proteins of all viruses involve in the interaction or whether the viruses are from the same or different ones. The peptide expressed from the proteins and the different mutations of deletion, substitution and insertion of a peptide sequence
- 2) The specification failed to provide any working examples of any other viruses except for hepatitis, as stated above.
- 3) The state of the prior art is such that techniques for the determination of the different protein-protein interactions have not been a priori determined.
- 4) The art of protein interactions is inherently unpredictable. For example, protein folding could result in a deleterious effect. This is recognized by applicants at e.g., at page 10, line 10 of the instant specification. Applicants state that "mis-folding of the hybrid proteins could prevent the detection of protein interactions.... A problem with this approach is that some of the interactions detected by screening randomly generated libraries may be completely unrelated to a biological

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protein:protein interaction. That is part of the wider problem of identifying, among positive clones in a two-hybrid screen, those having a biological relevance...."

6) The level of skill in the art is high, but the protein art is so unpredictable that it would require undue experimentation to make the invention commensurate in scope with that claims.

7) The specification lacks sufficient guidance or direction as how to determine the applicability of the single embodied species to the broad scope of the claims.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-9 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claims 1 and 6 are indefinite in that the steps are incomplete for failing to recite detection of the protein-protein interactions as recited in the preamble. The body recites for a genomic viral DNA fragments and not a protein. Also, the body of the claim recites for assaying by two-hybrid screening of the library of DNA, not protein. It is not clear, within the claimed context, the proteins involved in said interactions.

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B). The limitation set forth in claim 4 is confusing and unclear as to how it further limits the base claim and appear to broaden the base claim. The base claim does not recite a precursor polyprotein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 6-9 are provisionally rejected under the judicially created doctrine of double patenting over claims e.g., of copending Application No. 09/921,397 (US published application 20020151484) ('484 application). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending

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application since the referenced copending application and the instant application are claiming common subject matter, as follows: a method of detecting viral-viral protein interactions is disclosed at paragraph [0035]-[0050] of the '484 published application.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Fischer et al (Virus Genes) or

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Matsumoto et al (Jrnl. Of Virology) in view of Bartel (Nature generics) or Lecrenier (Bioassays, 1998).

Each of Fischer and Matsumoto discloses a method of detecting protein-protein interaction of HCV except each of these references fails to disclose that the protein-protein interactions are from a random library of DNA-binding domains and activation domain vector (i.e., a two hybrid system). However, Bartel discloses at e.g., page 72, col. 1 that in the conventional two-hybrid search, a known protein that forms part of a DNA-binding domain hybrid is assayed against a library of all possible proteins present as transcriptional activation domain hybrids. Furthermore, Bartel at e.g., page 73, col. 2 discloses a screening strategy wherein a randomly generated fragments of DNA cloned into DNA-binding domain and activation domain vectors are screened against each other. Bartel discloses that the two-hybrid method could be more readily scaled up; requires far fewer cloning steps, provides data on domains mediating interactions and allows fragments of proteins to be assayed in cases in which the full-length proteins, when fused to a DNA-binding domain, activate transcription on their own. Lecrenier at page 1 discloses that the yeast two-hybrid system is a genetic method that detects protein-protein interactions using the virus herpes simplex VP16 protein as the activation domain. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention

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was made to use a random library of DNA and activation domain in the HCV two hybrid screening of either Fischer or Matsumoto for the advantages disclosed by Bartel. The numerous advantages derived from the use of random libraries in the known two-yeast hybrid method would motivate one having ordinary skill in the art.

Claims 22-24 are free of prior art.

[Applicants are requested to resubmit PTO-1449 to make of record the references cited therein.]

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Worman discloses viral protein interactions using two-hybrid assay.


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
September 24, 2005